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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,435	03/29/2001	Michael Clare-Salzer	UF-160CD2	1769

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 821,435	Applicant(s) CLARE-SALZER
Examiner SAUNDERS	Group Art Unit 1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 10/14/03
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 4, 6-8, 10 is/are pending in the application.
- ☐ Of the above claim(s) is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 1, 6, 10 is/are rejected.
- ☒ Claim(s) 4, 7-8 is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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Amendment of 10/14/03 has been entered. Claims 1, 4, 6-8 and 10 are pending and under examination.

The amendment has entered no new matter.

The amendment has overcome 112, first paragraph rejections of record and all prior art rejections of record except for that stated infra.

Claim 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuruvilla et al, Racke et al or Johns et al.

Claims 1 and 6 previously rejected over these references for showing the use of TGF-B to treat or inhibit development of EAE. The added limitation of claim 1, that "the autoimmune disease is not multiple sclerosis", does not overcome because EAE is, strictly speaking, "not multiple sclerosis." The former is a disease spontaneously appearing in humans; the latter is an induced disease in experimental animals. Giving the broadest reasonable interpretation to the term "not multiple sclerosis", the examiner is thus correct in maintaining the rejection.

Applicant's urgings filed on 10/14/03 have been considered but are unconvincing of patentability.

The terminal disclaimer filed on 10/14/03 has been accepted.

Claims 1, 6 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Bentz et al (5, 008, 240, newly cited).

Bentz et al teach administration of CIF (TGF-beta) to treat various autoimmune diseases (see col.8, lines 17-52). Bentz et al use the term treat to mean "prophylaxis" (col.2, lines 57-61), which is consistent with instant recitation of "inhibiting." Example 5

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shows use of CIF (TGF-beta) in treating ECIA in experimental rats. While the disease has been induced by collagen injection and the rats show some signs of disease at the point of CIF administration, it is clear that the administration thereof inhibits further development of the disease---e.g. reduced antibody titres are observed in treated rats. This effect is consistent with the broadest reasonable interpretation of the term "inhibiting the development" in instant, claim 1. Applicant is also referred to Kraus et al (of record) at page 689, col.2 for showing the equivalence of CIF and TGF-beta.

Claim 6 is rejected since an autoantigen (collagen) is administered in example 5 and since the claim is not specific as to whether administration of autoantigen is intended to induce or attenuate the disease process.

Claim 10 is included, given the listing of autoimmune diseases at col.8.

Since applicant's claims were previously diffuse, citation of a new reference is proper.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on alternative Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/tgd

February 23, 2004

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182-1644